UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	))))	MDL NO. 2272
This Document Relates to the Below Listed Cases	)))	Master Docket Case No. 1:11-cv-05468 Honorable Rebecca Pallmeyer

James Krammes, et al. v. Zimmer, Inc., et al., 1:11-cv-05488
Beverly Goldberg v. Zimmer Holdings, Inc., et al., 1:11-cv-06425
Margaret Loveday, et al. v. Zimmer, Inc., et al., 1:11-cv-05752
Victoria Messina, et al. v. Zimmer, Inc., et al., 1:11-cv-06423
Corda B. Gaddy v. Zimmer, Inc., et al., 1:12-cv-00089

ZIMMER'S[1] SUPPLEMENTAL RESPONSE
IN SUPPORT OF ITS MOTION FOR SUGGESTION OF REMAND

I. INTRODUCTION

Based on a broad defect argument unsupported by any of the sources they cite, Plaintiffs ask the Court to request the JPML to reverse its prior rulings and expand the scope of this MDL in a way that would invite reopening all the document discovery already done, expand the case from 7 components to 21, and thereby derail and delay this case. There is no benefit to be gained from such disruption.

Contrary to Plaintiffs' assertions in their Supplemental Brief In Opposition To Defendants' Motion For Suggestion of Remand ("Supplemental Opposition"), Zimmer Entities'

[1] For purposes of this supplemental response, "Zimmer " includes the following defendants: Zimmer, Inc., Zimmer Holdings, Inc., Zimmer Surgical, Inc., f/k/a Zimmer Orthopaedic Surgical Products, Inc., Wilson/Phillips Holdings, Inc., d/b/a Zimmer Wilson/Phillips, Orthopaedic Technologies, LLC, d/b/a Zimmer Tri-State (incorrectly named as (1) Zimmer Tri-State d/b/a Tri-State Orthopaedic, (2) Zimmer Tri-State d/b/a Zimmer, Inc., and/or (3) Zimmer Tri-State d/b/a Tri-State Orthopedic), K. Michael Melia, d/b/a Zimmer Melia & Associates, Inc. (incorrectly named as Zimmer Melia & Associates, Inc.), Zimmer Orthobiologics, Inc., Zimmer US, Inc., and Zimmer Production, Inc.

Motion For Suggestion Of Remand ("Motion For Remand") does not rely on any "denial of physics" or "sleight of hand." Rather, Zimmer, when afforded the opportunity to inspect medical records in some of the cases in this MDL, found that those cases fell outside of the clearly and repeatedly defined boundaries of the MDL as set by the JPML. Zimmer then followed the most conservative procedural approach available and asked this Court to suggest to the JPML that those cases be remanded. Almost one-half of the Plaintiffs with cases at issue in the Motion For Remand have either stipulated to the Motion or voluntarily dismissed their cases altogether. Five cases remain at issue.

Zimmer's Motion For Remand and Zimmer's Reply To Certain Plaintiffs' Responses To The Zimmer Entities' Motion For Suggestion Of Remand ("Reply In Support") detail the JPML's numerous entries enforcing the limited scope of this MDL and expressly rejecting "system" theories. Motion For Remand, Dkt. 237, at 3-6; Reply In Support, Dkt. 479, at 2-3. After the June 1 status conference, the JPML issued yet another order refusing to expand the scope of the MDL to include any concept of the NexGen "system" and instead limiting the MDL to the loosening of specific components (the "MDL Products"). Order Vacating Conditional Transfer Order re *Gene Wernette et al v. Zimmer, Inc., et al.*, JPML Dkt. 669, attached hereto as Exhibit 1. In that order the Panel again held that Zimmer's interpretation of the limited scope of the Panel's Transfer Order is correct.

This Court made a similar observation at the June 1 status conference:

> But what [the MDL transfer order] says is that the common issues are the allegation that the components are prone to premature loosening and whether the components actually provide an increase in flexion. It really doesn't use the word "system" and doesn’t suggest that what we are talking about it whether the system has sort of generalized failure.

Tr. 22:22 – 23:6

The Court's stated inclination was correct: this MDL should not be expanded to a catch-all for every claim that revision of any of the dozens of NexGen products reflects an actionable product failure.

As the Court is aware, cases involving two fact patterns remain at issue in the Motion For Remand. In the first (*Krammes*), there are no MDL Products at issue: no flex femoral components and no 5950 MIS tibial components. In the second (*Gaddy, Goldberg, Messina, and Loveday*[2]), Plaintiffs received a flex femoral component, but it did not loosen and was not revised. Instead some other component – not an MDL Product but some other tibial component or articular surface – was replaced.

Neither fact pattern fits this MDL.

II. THE MDL COURT'S AUTHORITY

In their Supplemental Opposition, Plaintiffs have stated without authority that this Court should not suggest remand if the cases involve "some common questions of fact," Supplemental Opposition at 3-4, or if there is "overlap in the pretrial proceedings." *Id.* at 4. In fact, the standard for deciding the Motion For Remand is the same as the standard for remand employed by the Panel itself. *In re Bridgestone/Firestone, Inc., ATX, ATX II, and Wilderness Tires Prods. Liab. Litig.*, 128 F. Supp. 2d 1196, 1197 (S.D. Ind. 2001). That standard is whether the centralization "will be for the convenience of the parties and the witness and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407 (a); *In re Air Crash Disaster at Tenerife, Canary Islands on March 27, 1977,* 461 F.Supp. 671, 672 (J.P.M.L. 1978) ("We find that remand … will serve the convenience of the parties and witnesses and will promote the just

[2] Plaintiffs referenced only three cases in this group in their Supplemental Opposition: *Goldberg*, *Messina,* and *Loveday*. Zimmer knows of no reason why the *Gaddy* case is not still at issue.

and efficient conduct of [the case]. Accordingly, we order remand. . . ."). Or, as stated by the Manual for Complex Litigation, the transferee court should "consider when remand will best serve the expeditious disposition of the litigation." Manual For Complex Litigation, Fourth Ed., § 20.133. In short, the standard is whether or not the benefit of centralization is outweighed by the costs of managing the centralized litigation. *See generally*, *In Re Concrete Pipe*, 302 F. Supp. 244, 254-256 (J.P.M.L. 1969) (Wiegel, J., concurring).

Because there are no material common issues in the proposed expanded scope, the burden of expansion would outweigh any limited efficiency to be gained.

III. KRAMMES SHOULD BE REMANDED

There is no meaningful connection between Mr. Krammes' case and the other cases in this MDL. *Krammes* involves no MDL component. Instead, Mr. Krammes complains of loosening of a non-MDL Product: the 5954 tibial component.[3] Mr. Krammes' case is so dissimilar that he could not even join in the Master Long Form Complaint. Mr. Krammes' Motion For Leave To File An Amended Short Form Complaint ("Motion For Leave To File Amended Short Form Complaint"), Dkt. 25, 1:11-cv-05488, attached at Exhibit 2, stated that "[t]he instant case is unique . . . . ," and that he "would be compromised by adopting COUNT III (e) Strict Liability Manufacturing Defect of the Master Complaint because it does not contemplate the manufacturing defect specific to the MIS trabecular metal tibial tray." *Id.* at ¶¶ 13-14.

Plaintiffs acknowledge that including cases with the 5954 MIS tibias and a non-flex femoral component will expand discovery. They propose that the inclusion of such cases could be accommodated by "separate discovery schedules or having separate tracks for each

[3] The 5954 was the subject of a limited manufacturing recall unrelated to any MDL component.

device." Supplemental Opposition at 4. If these cases were truly as similar as Plaintiffs claim, and the efficiencies were as real, no such separate schedules or tracks would be needed.

Moreover, *Krammes* is unique even among 5954 cases. Based on the records received since Zimmer filed its Motion For Remand, 25 Plaintiffs received a 5954 trabecular metal tibia. Declaration of Nicole E. Brett ("Brett Decl."), ¶ 4, attached as Exhibit 3. Of those 25 devices, Krammes is the only plaintiff who received a 5954 from the limited lot manufacturing recall that affected Krammes' device. *Id.* Krammes specifically alleges that the revision of his knee implant was due to the precise reason for the limited lot manufacturing recall. Motion For Leave To File Amended Short Form Complaint, ¶¶ 10-12. Creating a separate discovery track for a single case in which liability is based on a unique and specific theory of defect is certainly not an efficient use of this Court's resources.

IV. CASES IN WHICH NO MDL PRODUCT LOOSENED SHOULD BE REMANDED

A. Plaintiffs' Conclusory Argument That Flex Femoral Components Cause Tibial Loosening Is Not Sufficient To Create A Meaningful Common Issue Here

Plaintiffs' supplemental briefing claims "signature injuries" due to the NexGen system beyond the specific component loosenings that define the present scope of this MDL. Central to Plaintiffs' argument is their pure argument – and it is nothing more than that – that the design of the flex femoral component causes loosening of the tibial tray.

Despite broad unsupported statements claiming Zimmer ignores "scientific evidence, biological plausibility . . . [and] Zimmer's own design rationale,"[4] the Plaintiffs produced only their lawyers' conclusions as to any connection between the design of the flex femoral component and an increased risk of tibial loosening. Plaintiffs spend pages speculating about a potential connection based on the obvious and unremarkable fact that, in a total knee

[4] Supplemental Opposition at 1.

replacement, the tibial tray component bears loads. Supplement Opposition at 6-10 (citing documents showing that tibial components must bear loads).

Plaintiffs argue for a broader scope based on the claim of an empirical link between MDL issues and their outside-the-scope cases through specified science and Zimmer testing documents. Plaintiffs' characterization is incorrect. The documents do not establish such a link. To the contrary, much of the literature cited addresses femoral loosening, not tibial loosening at all. Similarly, the fact that Zimmer tests for tibial load is unremarkable and by itself does not provide any connection between the MDL and the proposed claims.

Plaintiffs will argue, incorrectly, that Zimmer is demanding that Plaintiffs must actually prove their "system failure" theory in order to expand the scope of the MDL. This is not so. Instead, Zimmer asks only that the Court take Plaintiffs' cited articles at face value. The science Plaintiffs cite in their Supplemental Opposition simply does not stand for the propositions for which Plaintiffs cite it.

For one example, at the June 1, 2012 status conference, Plaintiffs' counsel stated, "There is a published article, at least with respect to MIS, that the Flex done by MIS shows an increased risk of loosening of the tibia." Tr. 26-21:23, emphasis supplied. Plaintiffs later provided Zimmer two cites for the articles they were referring to:

- *Toshiro, Y., et al.*, Minimally Invasive Versus Standard Approach in Total Knee Arthroplasty, [Clinical Orthopaedics And Related Research], Number 463, pp. 144–150, attached as Exhibit 4; and
- *Barrack, R. et al.*, Minimal Incision Surgery as a Risk Factor for Early Failure of Total Knee Arthroplasty, Journal of Arthroplasty 24:489-498 (2009), attached as Exhibit 5.

Plaintiffs cited neither article in their Supplemental Opposition, probably because contrary to Plaintiffs' characterization at argument neither article says a word about the impact of

flex femoral components[5] on tibial loosening. Instead, both studies concern the effectiveness of minimally invasive surgery techniques (and in fact neither comes to negative conclusions). The *Toshiro* study, which reviewed surgeries involving Zimmer NexGen devices, states in its abstract "We believe the minimally invasive technique positively contributes to the early restoration of quadriceps strength and a speedy return to normal function." Exhibit 4 at p. 144 The *Barrack* study, which did not even involve the use of Zimmer products, found no statistically significant difference in the number of revisions due to loosening for MIS and non-MIS surgeries. Exhibit 5 at p. 492, tbl. 1, ln. 7.

Similarly, the flex femoral component studies Plaintiffs have cited throughout this case themselves found no incidence of increased tibial loosening. *Han, et al., High Incidence Of Loosening Of The Femoral Component in Legacy Posterior Stabilized-Flex Total Knee Replacement,* 89-B J. BONE JOINT SURG. [BR], 1457, 1458-59 (2007) ("… tibial base plates, which were well-fixed"); *Cho, et al., Three- to six-year follow-up results after high-flexion total knee arthroplasty: can we allow passive deep knee bending?*, 19 KNEE SURG SPORTS TRAUMATOL ARTHROSC 899 (2010) (finding possible loosening only of femoral components).

Plaintiffs' Supplemental Opposition discusses at length Zimmer's careful attention to the design and testing of both its tibial components and its flex femoral components to ensure those components were and are both safe and effective. Supplemental Opposition at 6-10. For instance, Plaintiffs devote nearly a page of their Supplemental Opposition to Zimmer's design rationale for the NexGen device. *Id*. at 7. However, this design rationale simply indicates that Zimmer carefully considered and tested its devices to make sure they work. Zimmer has attached the design rationale hereto as Exhibit 6. Nowhere does it support Plaintiffs' theory that

[5] Again, at this stage Zimmer takes the studies at face value.

the flex design causes increased tibial loosening. The same is true of the cited deposition testimony, citations to Zimmer's own technical memorandum, and the literature they quote. None of these has anything to say about flex femoral components causing increased tibial loosening.

Plaintiffs are left with only their counsel's theories to support a finding of a common issue sufficient to force a significant expansion of this case. That is not enough.

B. The Continued Centralization Of Cases With No Loosened MDL Product Will Be Inefficient

When Zimmer filed its Motion For Suggestion Of Remand in February 2012, it included every case for which it had sufficient evidence to determine that the cases fell outside of the scope of the MDL as set by the JPML.[6] Per the Court's request at the June 1st status conference, Zimmer is now aware of 42 out of 588 cases with the same fact pattern as *Gaddy*, *Goldberg*, *Loveday*, and *Messina*: patients received a flex femoral component, but, even though they underwent a revision surgery, the flex component was not loose and was not revised. Brett Decl. at ¶5. These 42 cases involve the revision of 14 different products: 9 different tibial components, 3 different articulating surfaces, 1 patella, and 1 poly locking screw. *Id. at* ¶ 7. Plaintiffs claim that this diversity of products is no matter, because "Plaintiffs are not alleging that the tibial component is defective." Supplemental Opposition p. 10 n. 2.

Plaintiffs' claims to efficiency, however, are belied by their advocacy of multiple discovery tracks in this MDL. If Plaintiffs truly intend to claim no tibial defect (with the

[6] Plaintiffs argued at the June 1 status conference that Zimmer should have known from the face of the Complaints in *Loveday* and *Messina* that the MDL Product each plaintiff received had not been revised. Tr. 43-44. This is simply not so. The Complaints in *Loveday* and *Messina* both plainly state that the Plaintiffs' flex devices were revised. Both complaints are nearly identical. Both define the "LPS-Flex Femoral Component" as "Zimmer NexGen LPS Flex" in paragraph 1, and then state in paragraph 36, ". . . Plaintiff had a second surgery to revise/replace her previously implanted Zimmer NexGen LPS Flex." Only later did Zimmer learn this was not so, that only the non-5950 tibia was revised.

exception of the 5950 and 5954) then multiple discovery tracks would not be needed. If additional tracks in this MDL were created, they would be incredibly inefficient.

A complete breakdown of the tracks that would need to be created and the number of cases for each product is below:

1. Tibial Components:
    a. 5886 (NexGen TM Monoblock Tibial Component) – 3 cases
    b. 5970 (NexGen CR Pegged Tibial Component Precoat – 4 cases
    c. 5916 (NexGen Fluted Stem Mobile Tibial Component Option) – 2 cases
    d. 5954 (NexGen TM Tibial Tray) – 2 cases
    e. 5980 (NexGen Stemmed Tibial Component Precoat) – 9 cases
    f. 5982 (NexGen Stemmed Tibial Component Porous) – 1 case
    g. 5986 (NexGen Stemmed Nonaugmentable Tibial Component Option) – 3 cases
    h. 5996 (NexGen Fluted Stemmed Tibial Component Option) – 1 case
    i. Unknown tibial component (not alleged to be 5950) – 1 case
2. Articular Surface:
    a. 5952 (NexGen Prolong CR-Flex Articular Surface – 3 cases
    b. 5962 (NexGen LPS-Flex Articular Surface) – 5 cases
    c. 5964 (NexGen LPS-Flex Articular Surface) – 4 case
3. Patella:
    a. 5972 (NexGen All Poly Patella) – 3 cases
4. Other:
    a. 5950 (NexGen MIS Flex Locking Poly Screw) – 1 case

Brett Decl. at ¶ 7.

The expansion of scope that Plaintiffs seek will undermine the significant progress to date in this MDL. The scope of discovery so far has been governed by issues around the loosening of the seven products as identified by the JPML. *See, e.g.*, CMO3, Section II(a)(4) (sustaining Zimmer's objection to production of witness for tibial components beyond the 5950 at issue in the case), Dkt. 412, p. 2. Zimmer has produced well over 1,000,000 pages of actual documents, largely from 19 custodians already completed. Expansion of scope now to cover additional products will have at least two immediate and grossly inefficient consequences. First, it will inevitably lead Plaintiffs to demand that Zimmer go back and re-search, re-scan, and then produce more documents from the 19 custodians whose documents have already been produced. Great portions of many months' work will have to be re-done. Second, both the expansion of past production and of future production and depositions would slow discovery, will require re-negotiation of the custodian discovery schedule, and inevitably delay the schedule for discovery, *Daubert* motions, dispositive motions and trial settings on which the parties have now agreed.

V. CONCLUSION

The cases at issue in this Motion are outside the scope set by the MDL. The question before this Court is now whether it should ask the Panel to expand that scope and thereby derail this case. As to *Krammes,* there is no efficiency to be gained by keeping a unique case with a unique theory of defect in this MDL, and this Court should suggest remand. As to the cases where no MDL Product has loosened, the Plaintiffs have failed to provide any real common theory of defect, and even taken at face value the "science" they offer in support simply does not say what Plaintiffs claim it says. The more efficient method of handling these cases,

which fall outside the scope of the JPML's Transfer Order, is that they be managed as individual cases in the courts from which they came.

Respectfully submitted,

Dated: July 6, 2012

FAEGRE BAKER DANIELS LLP

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CERTIFICATE OF SERVICE

I certify that on July 6, 2012, a copy of the foregoing Zimmer's Supplemental Response In Support Of Its Motion For Suggestion Of Remand was filed electronically. Parties may access this filing through the Court's system.

/s/ Joseph H. Yeager, Jr.